

EXHIBIT 1

Systemic Nanoparticle Albumin-Bound Paclitaxel (nab-Paclitaxel) for the Prevention of In-Stent Restenosis (SNAPIST-II): A Randomized Comparison of Single Dose and Single Dose Plus Repeat Dose at 2 Months

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Background: Safety of a single IV injection of nab-paclitaxel (ABI-007; CoroxaneTM) after de novo coronary stenting was established in SNAPIST-I (MacDonald, 2005). SNAPIST-II was initiated to compare the safety and efficacy of 1 versus 2 doses of nab-paclitaxel in patients with up to 2 stented lesions (≤ 25 mm length) in up to 2 de novo coronary arteries (≥ 2.5 mm diameter).

Methods: Patients were randomly assigned to IV treatment with either 1 dose of nab-paclitaxel 35 mg/m² immediately after successful, uncomplicated stenting or 1 dose at stenting plus a second dose 2 months later. Patients received aspirin and clopidogrel for 6 months. Primary endpoints were the safety of nab-paclitaxel and major adverse cardiac events (MACE: death, myocardial infarction [MI], coronary artery bypass grafting [CABG], target lesion revascularization [TLR], and target vessel revascularization [TVR]) at 2 months. Secondary endpoints were MACE and quantitative coronary angiographic (QCA) evaluation of restenosis at 6 months.

Results: Seventy-six patients (86% men, 11% with diabetes) aged 58 ± 10 years were enrolled. QCA at baseline (available for 75 patients, 81 lesions) showed reference vessel diameter 2.90 ± 0.54 mm, lesion length 10.16 ± 3.49 mm, and vessel minimum luminal diameter (MLD) 1.08 ± 0.47 mm pre-procedure and stent-MLD 2.77 ± 0.44 mm post-stenting. Only 1 serious toxicity (gastrointestinal bleeding) was considered possibly related to study drug. Most side effects were mild. No MACE were observed at 2 months; preliminary MACE at 6 months were TLR (6/73) and TVR (7/73). No patient died or had an MI or CABG on study. Treatment-related adverse events with a frequency of $\geq 3\%$ and MACE are reported for the two dose groups in the table below.

	1 Dose	2 Doses	p value
No. of treated patients (n)	38	38	
Drug Safety (n=76)			
Nausea	4(11%)	1(3%)	0.358
Fatigue	1(3%)	3(8%)	0.615
Lymphopenia	1(3%)	2(5%)	>0.999
Mild hair loss (scalp or body)	2(5%)	1(3%)	>0.999
MACE 2 month (n=76)	0/38	0/38	
Preliminary MACE at 6 month (n=73)	2/37	5/36	0.261
TLR	2/37	4/36	0.430
TVR	2/37	5/36	0.261

Conclusions: nab-Paclitaxel administered IV at 35 mg/m² (1 or 2 doses) appears to be well tolerated with no significant differences in drug safety. TLR/TVR rates were encouraging. Although not statistically significant, preliminary 6-month MACE data showed fewer TLR/TVR for the single dose group. However, this needs to be verified by QCA. Complete data including 6-month QCA for the two groups will be available for presentation.